

Curriculum Vitae

Grace T. Bartoo, Ph.D., R.A.C.

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Education

Regulatory Affairs Certification

Ph.D., Bioengineering, University of Washington, Seattle, WA

Dissertation: Quantitative Neuropathological Measures in Alzheimer's Disease

M.S., Electrical Engineering, University of Washington, Seattle, WA

Thesis: Automated Detection of Senile Plaques in Alzheimer's Disease Using Image Analysis

B.S. with Honors, Bioengineering, University of California, Berkeley, CA

Professional Experience

1998 – present

Vice President, Clinical and Regulatory Affairs

Instrumentation for Science & Medicine, Inc., San Carlos, CA

I am a senior partner in this medical device consulting firm. For our clients, I have provided services in the areas of regulatory strategy, 510(k) and PMA submissions, project management, statistical, data analysis, quality (verification and validation), study design, and study monitoring. Internally I am responsible for setting up and implementing the company's quality system, and also all financial operations.

1993 - 1998

Clinical Research Consultant

Bartoo Biomedical

Provided over 2,000 hours of service, primarily with a client on a class III medical device clinical trial. I worked with a team of statisticians and clinicians to design the studies. I also wrote protocols and study manuals, designed case report forms, prepared submissions and made presentations to the Food and Drug Administration. I managed the preclinical trials which consisted of approximately 40,000 cases from three trial sites and was completed in approximately six months.

1995 - 1996

Program Manager, Commercialization

1988 - 1992

Technical Founder, Director of Clinical Affairs

NeoPath, Inc., Bellevue, WA

As a founder and the first employee of this venture capital financed company, I played a key role in this growing company, which has successfully raised over \$70 million and is publicly traded. The company developed a cervical smear analyzer, which incorporates innovative mechanical, optical, electronic and pattern recognition technologies. As the company grew from the start up stages, I became the Director of Clinical Affairs, where I was responsible for basic clinical research and clinical trials.

I left the company to complete my Ph.D. and was rehired after graduation as Program Manager. I was responsible for the programs/projects required to commercialize the cervical smear analyzer in the United States, Australia, and Europe. Assembling teams from multiple departments, my responsibilities included setting up the infrastructure required for commercialization such as a customer and technical support system;

introducing the first devices into commercial sites and coordinating evaluation studies; conducting and presenting analyses of strategic corporate issues for executive management; setting the corporate goals for the employee bonus program; and evaluating the company's progress towards meeting those goals.

Research Assistant

University of Washington Alzheimer's Disease Research Center, Seattle, WA

During my graduate studies, I developed a semi-automated image analysis system that quantifies the amount of protein deposits on immunohistochemical sections of the human brain. Development of this system included the development of a microcomputer-controlled three-dimensional stage, generation of the control software, and design and implementation of image analysis software. I used this system in a variety of biological experiments, including research in Alzheimer's disease and mathematical modeling of brain tumor growth. During my research studies, I was based in the Neuropathology laboratory and also conducted research on neoplastic diseases, especially gliomas.

Intern

IBM Palo Alto Scientific Center, Palo Alto, CA

I designed and implemented a novel software algorithm for semi-automatic spatial registration of MRI, CT and SPECT brain images on the IBM 5090. I also conducted a study comparing this algorithm against manual image registration.

1982 - 1986

Research Engineer

MedaSonics, Inc., Milpitas, CA

I was the project engineer for the company's first software product, a database management system based upon the IBM PC. The product included menu driven graphical user interfaces, custom reports, database query, and advisory diagnosis capabilities. As part of this project, I worked closely with multiple departments and accomplished the following: developed the product concept; managed a team of engineers and technicians; programmed and validated software; wrote and produced user manuals; wrote standard operating procedures (SOPs); supported formal release of the product; conducted training of national sales and clinical staff; and supported clinical testing of the product.

Teaching Experience

University of Washington, Seattle, WA

1994 - 1995 Supervisor -- Independent Study (BIOENG 499)

1988 Teaching Assistant -- Functional Human Neuroanatomy (CONJOINT 511)

1987 Teaching Assistant -- Image Processing Workshop (UW Extension)

Honors and Awards

Finalist, IEEE Engineering in Medicine and Biology Society International Student Paper Competition.

W. M. Keck Foundation Predoctoral Fellowship

ITBM- and IEEE-Sponsored National Bioengineering Student Paper Competition.

Selected as a semi-finalist to present paper at Paris conference.

Society of Women in Engineering Award

United Technologies Scholarship

University of California Alumni Scholarship

Grants

Image Analysis of Immunocytochemical Markers in Alzheimer's Disease

Principal Investigator: David Nochlin, M.D., University of Washington
 Capacity: Co-Investigator
 Role: Wrote significant portions of grant proposal (Materials and Methods, and Preliminary Results), coordinated image analysis, wrote image analysis programs, conducted data analysis.
 Agency: National Institute of Aging
 Grant Period: April 1994 - April 1995

Alzheimer's Disease Research Center, Core D, Neuropathology

Principal Investigator: Shuzo Mark Sumi, M.D., University of Washington
 Capacity: Consultant
 Role: Wrote portions of grant proposal, plan image analysis experiments, consult on data analyses, author publications.
 Agency: National Institute of Aging
 Grant Period: May 1995- May 1999

Professional and Community Service Activities

2004	Theme Chair, Industrial Applications and Chair, Industrial Activities, IEEE Engineering in Medicine and Biology Conference, San Francisco, CA , Sept. 2004
2003	Theme Chair, Industrial Applications, IEEE Engineering in Medicine and Biology Conference, Cancun, Mexico, Sept. 2003
2002 – present	Columnist, Regulatory Affairs, Engineering in Medicine and Biology Magazine.
2000 – present	Region 6 Representative, IEEE Engineering in Medicine and Biology Society – Administrative Committee (AdCom) Voting Member
2000 – 2002	Chair, Professional Activities Committee, IEEE Engineering and Medicine and Biology Society
2000-2001	Vice Chair, IEEE Santa Clara Valley Engineering in Medicine and Biology Society
1999 - 2000	Chair, IEEE Santa Clara Valley Engineering in Medicine and Biology Society
1996 - 1998	Governor (School Board), Fishergate Primary School, York, England
1995 - 1996	Consultant, Alzheimer's Disease Research Center, University of Washington, Seattle, Washington

- 1994 Referee, *IEEE Transactions in Biomedical Engineering*.
- 1991 - 1995 Image Analysis Consultant, UW Child Development Mental Retardation Center, Neuroscience Imaging Core.
- Coordinator and Chair of Student Professional Awareness Conference (S-PAC) held during IEEE Engineering in Medicine and Biology Society (EMBS) 11th Annual International Conference. Over 60 people attended the S-PAC conference, which included guest speakers from academia and industry.
- Co-coordinator of student volunteer group that supplied the audio visual services for the IEEE/EMBS 11th Annual International Conference.
- Officer of IEEE UW Student Chapter. Activities included participating in scholarship recipient selection and student social activities coordination.
- Student representative on UW Bioengineering Curriculum Committee.
- Treasurer of IEEE Silicon Valley Chapter of EMBS. Activities included coordinating monthly meetings with guest speakers and yearly one day symposiums, as well as financial responsibilities.

Publications

6. Bartoo GT. Risk management. *IEEE Eng Med Biol Mag*. 2003 Jul-Aug;22(4):166-70, 172.
5. Bartoo GT. Design controls. *IEEE Eng Med Biol Mag*. 2003 Mar-Apr;22(2):112-4.
4. Bartoo GT, Nochlin DN, Chang D, Kim Y, Sumi SM, Martin GM. The Mean A β Load in the Hippocampus Correlates to Severity of Dementia in Alzheimer's Disease. *Journal Neuropathology and Experimental Neurology*. vol. 56, pp. 531 - 540, 1997.
3. Tracqui P, Cruywagen, GC, Woodward DE, Bartoo, GT, Murray JD, Alvord, EC. A Mathematical Model of Glioma Growth: The Effect of Chemotherapy on Spatio-Temporal Growth. *Cell Proliferation*. vol. 28, pp. 17 - 31, 1995
2. Bartoo GT, Lee JSJ, Bartels PH, Kiviat NB, and Nelson AC. Automated Prescreening of Conventionally Prepared Cervical Smears: A Feasibility Study. *Laboratory Investigation* vol. 66(1) pp. 116 - 122, 1992.
1. Bartoo GT, Kim Y, Haralick RM, Nochlin D, Sumi SM. Mathematical Morphology Techniques for Image Processing Applications in Biomedical Imaging. *SPIE* vol. 914 pp. 466 - 475, 1988.

Invited Lectures

Topic: Image Analysis in Alzheimer's Disease

19. University of Washington Weekly Medical Imaging Seminar, Seattle, WA, 1995
18. Axon Instruments, Foster City, CA, 1995
17. University of Washington Electrical Engineering Weekly Seminar on Imaging, Seattle, WA, 1994.
16. Alzheimer's Disease and Related Disorders of Aging CME Course, Seattle, WA, 1993.
15. University of Washington Center for Bioengineering Faculty/Student Retreat, Seattle, WA, 1993.
14. Friends of Alzheimer's Disease Research, Seattle, WA, 1989.
13. University of Washington Electrical Engineering Weekly Seminar on Imaging, Seattle, WA 1989.
12. University of Washington Primate Center, Seattle, WA 1988.
11. Merck and Co., Philadelphia, PA 1988.
10. University of Washington Pathology Presents Seminar, Seattle, WA 1988.
9. Alzheimer's Disease Research Center Seminar, Seattle, WA 1988.

Topic: Automation of Cervical Smear Screening

8. University of Washington Electrical Engineering Weekly Seminar on Imaging, Seattle, WA, 1991.
7. Mountain States Association of Cytotechnology, Albuquerque, NM, 1990.
6. Pacific Northwest Cytotechnologists Association, Seattle, WA, 1989
5. New York State Department of Health, Albany, NY, 1989

Topic: Other

4. "Journeys – Grad School and Beyond,"
University of Washington Weekly Seminar on Bioengineering, Seattle, WA 2000.
3. "Biological Applications of Microscopic Imaging,"

Pacific Northwest Electron Microscopy Society Regional Conference, Seattle, WA 1994.

2. "Anatomy of a Start Up,"
University of Washington Bioengineering Student Association, Seattle, WA, 1991.
1. "Applications of Mathematical Morphology Techniques in Image Processing,"
IBM Palo Alto Scientific Center, Palo Alto, CA 1988.

Abstracts (Platform or Poster Presentations)

- 19..Katsnelson Y, Lapshin V, Claude J, and Bartoo GT. Transcranial .Electrotherapy Stimulation Device for the Temporary Reduction of Pain. 25th Annual International Conference Engineering in Medicine Conference, Cancun, Mexico (submitted).
18. "Quantitative Imaging for Clinicopathological Correlates in Alzheimer's Disease." Bartoo GT and Kim Y.. 17th Annual International Conference Engineering in Medicine and Biology Conference, Montreal, Quebec, Canada. Sept. 19-23, 1994, speaker.
17. "Image Analysis Measurements of A-Beta and Tau Load in Alzheimer's Disease and Elderly Controls." Bartoo GT, Nochlin D, Sumi SM. XII International Congress of Neuropathology, Toronto, Ontario, Canada. Sept. 18-24, 1994, poster.
16. "A Mathematical Model of the Effect of Chemotherapy on Glioma Growth." Bartoo, GT, Alvord EC, Woodward DE, Tracqui P, Cruywagen GC, Murray JD. XII International Congress of Neuropathology, Toronto, Ontario, Canada. Sept. 18-24, 1994, poster.
15. "A Mathematical Model of the Effect of Surgical Resection on Gliomas." Alvord EC, Bartoo GT, Woodward DE, Tracqui P, Cruywagen GC, Murray JD. XII International Congress of Neuropathology, Toronto, Ontario, Canada. Sept. 18-24, 1994, poster.
14. "Resection of Gliomas and Life Expectancy." Cook J, Woodward DE, Tracqui P, Cruywagen GC, Murray JD, Bartoo GT, Alvord EC. XII International Congress of Neuropathology, Toronto, Ontario, Canada. Sept. 18-24, 1994, poster.
13. "The Correlation of Tau and A β in Alzheimer's Disease." Bartoo GT. Pacific Northwest Alzheimer's Disease Research Symposium. June 1993, speaker.
12. "The Prevalence Distribution of Isolated SIL Cells on Conventional Cervical Smears." Bartoo GT, Hughes JP, Mauney M, Kiviat NB, Brancheau D, and Tucker JT. 39th Annual Meeting of the American Society of Cytology, Los Angeles, CA, Sept. 1991, poster.
11. "Automated Microimaging Systems for Pathology Laboratories." Nelson AC, Bartoo GT, Lee JSJ. Association for Advancement of Medical Instrumentation 25th Annual Meeting & Exposition, Anaheim, CA May 5-9, 1990, speaker.

10. "Mathematical Morphology Techniques for Image Processing Applications in Biomedical Imaging." Bartoo GT, Kim Y, Haralick RM, Nochlin D, Sumi SM. SPIE Medical Imaging II: Image Formation, Detection, Processing and Interpretation, Newport Beach, Feb. 2-9, 1988, speaker.
9. "Multi-Modality Image Registration Using Centroid Mapping." Bartoo GT, and Hanson WA. IEEE Engineering in Medicine and Biology Society 11th Annual International Conference, Seattle, WA, Nov. 4-7, 1989, speaker.
8. "Morphological Image Analysis for Studying Alzheimer's Disease." IBartoo GT. IEEE Engineering in Medicine and Biology Society 10th Annual International Conference, New Orleans, LA, Nov. 4-7, 1988, speaker.
7. "Automated Quantitation of Senile Plaques and Neurofibrillary Tangles in Alzheimer's Disease by Image Analysis." Bartoo GT, Nochlin D, Kim Y, Sumi SM. 64th Annual Meeting of the American Association of Neuropathologist, Inc., Charleston, SC, June 9-12, 1988, poster.
6. "Automatic Identification of Senile Plaques in Alzheimer's Disease." Bartoo GT. ITBM Annual Conference, Paris, France, April 1987, speaker.
5. "Applications of Image Analysis in Neuropathology." Bartoo GT. Biomedical Advances Through the Use of Modern Imaging Methods Symposium, Seattle, WA, Sept. 24 - 25, 1987, poster.
4. "Development of Computer Systems for the Vascular Laboratory." Bartoo GT. 2nd International Vascular Symposium, London, England, Sept. 8 - 12, 1986, speaker.
3. "The Personal Computer: A Diagnostic and Research Tool for the Vascular Laboratory." Bartoo GT. 2nd International Vascular Symposium, London, England, Sept. 8 - 12, 1986, poster.
2. "The Personal Computer: A Valuable Diagnostic and Research Tool." Bartoo GT. 31st Annual Convention of the American Institute of Ultrasound in Medicine, Las Vegas, NV, Sept. 16-19, 1986, poster.
1. "Why Do We Need a Computer in Our Laboratory?" Tong G and Cox D. 29th Annual Convention of the American Institute of Ultrasound in Medicine, Atlanta, GA, Sept., 1984, poster.